K092573

510(K) SUMMARY - Nihon Kohden QP-160AK EEG Trend Program

JUL - 9 2010

Name and Address of Applicant
Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, CA 92610

Contact:
Steve Geerdes
Director, Regulatory Affairs
(949) 580-1555 ex. 3325
Fax: (949) 580-1550

Summary revised on 7/8/2010

Trade/Device Name:
Nihon Kohden QP-160AK EEG Trend Program

Common or usual Name:
Electroencephalograph (EEG)

Legally Marketed Predicate:
Nervus Monitor (K021185) commercial distribution certification dated July 12, 2002.

Grass Technologies TWin Neurotrac-III (K081551) commercial distribution certification dated December 24th 2008.

Natus Neuroworks (K092039) commercial distribution certification dated Febuary 22nd 2009.

Day One Medical CNS Monitor (K080217) commercial distribution certification dated November 5th 2008.

Intended Use:
The QP-160AK Trend program is a software-only device intended to be installed on the EEG-1200A series electroencephalograph to record, calculate, and display EEG data obtained from the EEG-1200A system. This device is intended to be used by qualified medical practitioners, trained in Electroencephalography, who will exercise professional judgment when using the information.
The intended use for each of the software's outputs is as follows:

- The EEG and aEEG waveforms are intended to help the user monitor the state of the brain.
- The user-defined Fast Fourier Transform (FFT) parameters of this software (FFT power) are intended to help the user analyze the EEG waveform.
- The burst suppression parameters of this software (interburst interval and bursts per minute) are intended to aid in the identification and characterization of areas of burst-suppression pattern in the EEG.

This device does not provide any diagnostic conclusion about the patient's condition to the user.

Device Description

Physical Description
The QP-160AK EEG Trend program is a software program stored on electronic media such as CD Rom.

Principles of Operation
The EEG-1200A QP-160AK Trend program is a device which is installed on the electroencephalograph EEG-1200A Series and records the EEG waveforms and identifies trends in the EEG data over extended periods of time in order for trained health care professionals to observe changes over time.

Design Features
The QP-160AK design features are as follows:

- Trend display of aEEG and Burst suppression ratio
- Display of EEG waveform maximum of 64 channels
- DC Trend display including analog inputs
- Operations of functions by control buttons adapted to touch panels
- Data management by NeuroWorkbench

A summary of the technological characteristics of the device compared to the predicate device:

The main difference between the new QP-160AK EEG Trend program and the predicate the Nervus Monitor is a different time interval of trends.

The main difference between the new QP-160AK EEG Trend program and the predicate device " Grass Technologies Neurotrac III is a different time interval of trends

The main difference between the new QP-160AK EEG Trend program and the predicate device "Natus Neuroworks is the Natus only provides aEEG elements of the QP-160AK

The main difference between the new QP-160AK EEG Trend program and the predicate device "Day One Medical CNS Monitor is a stand alone product.

COMPARATIVE INFORMATION

A. Intended Use

Nihon Kohden QP -160 Trends	**Carefusion Nervus Monitor**	**Grass NeuroTrac III**	**Natus Neuroworks**	**Day One Medical CNS Monitor**
510k Pending	***K-021185 (07-12-02)***	***K-081551 (12-24-08)***	***K-090019 (02-22-10)***	***K-080217 (11-05-08)***
aEEG	Yes (aEEG)	Yes (aEEG)	Yes (aEEG)	Yes (aEEG)
Burst Suppression Ratio	Yes (Burst Suppression Ratio)	Yes (Burst Suppression Index)	No	Yes (percent Suppression)

Inter-burst Interval	Yes (Burst Suppression)	Yes (Inter-Burst Interval)	No	Yes (Inter Burst Interval)
Burst per minute	Yes (Burst Suppression)	No	No	Unknown
FFT Power	Yes (Abs band power/Tower power)	Yes (FFT bands trends)	No	Yes (Total Power)
FFT Power Ratio (Alpha /Delta)	Yes (Alpha to Delta)	Yes (FFT bands trends)	No	Yes (EEG Band Power Percentages)
DC Trend including analog input	Yes (Generic trend)	Yes (DC Channel Display)	No	Yes (Serial input)

B. Physical Characteristics

Nihon Kohden QP -160 Trends	**Carefusion Nervus Monitor**	**Grass NeuroTrac III**	**Natus Neuroworks**	**Day One Medical CNS Monitor**
CD ROM or electronic media	Incorporate in the Monitor	CD ROM or electronic media	CD ROM or electronic media	Incorporate in the Monitor

C. Target Population

Nihon Kohden QP-160 Trends	**Carefusion Nervus Monitor**	**Grass NeuroTrac III**	**Natus Neuroworks**	**Day One Medical CNS Monitor**
1. Any location within a medical facility, physician's office, laboratory, clinic or nursing home.	Same	Same	Same	Same

Performance Testing

- To date no special controls or performance standards are known or established for this device as required by sections 513(b) and 514 of the Food, Drug and Cosmetic Act as implemented by 21 CFR Part 861.

- The device is not sterile.

- The device does not directly contact patients. Therefore, good laboratory practice studies were not required per 21 CFR Part 58.

- The QP-160AK EEG Trend Program was subjected to safety and performance testing procedures. The QP-160AK EEG Trend Program has undergone validation and

verification testing to ensure conformance to all design requirements. Additionally, the system has undergone comparison testing to ensure the substantial equivalence of the calculation and display of the burst suppression ratio and aEEG. These tests verified that the device performed within specifications.

Conclusion of Substantial Equivalence:

- The comparison of technological characteristics and performance testing of the QP-160AK EEG Trend Program demonstrate that its safety, effectiveness, and performance are equivalent to the specified predicate devices. Therefore, Nihon Kohden believes that the device is substantially equivalent to the Nervus Monitor, Grass Neurotrac III, Natus Neuroworks, and the Day One Medical CNS Monitor predicate devices as stated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Nihon Kohden America, Inc.
c/o Mr. Steve Geerdes
Director, Regulatory Affairs
90 Icon Street
Foothill Ranch, CA 9261 0

APR - 9 2012

Re: K092573
Trade/Device Name: Nihon Kohden QP-l60AK EEG Trend Program for the Nihon Kohden EEG-1200A Series Neurofax Electroencephalograph
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OMA, OLT, ORT
Dated (Date on orig SE ltr): June 30, 2010
Received (Date on orig SE ltr): July 1, 2010

Dear Mr. Geerdes:

This letter corrects our substantially equivalent letter of July 9, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K092573

Device Name: Nihon Kohden QP-160AK EEG Trend Program

Indications for Use:

The QP-160AK Trend program is a software-only device intended to be installed on the EEG-1200A series electroencephalograph to record, calculate, and display EEG data obtained from the EEG-1200A system. This device is intended to be used by qualified medical practitioners, trained in Electroencephalography, who will exercise professional judgment when using the information.

The intended use for each of the software's outputs is as follows:

- The EEG and aEEG waveforms are intended to help the user monitor the state of the brain.
- The user-defined Fast Fourier Transform (FFT) parameters of this software (FFT power) are intended to help the user analyze the EEG waveform.
- The burst suppression parameters of this software (interburst interval and bursts per minute) are intended to aid in the identification and characterization of areas of burst-suppression pattern in the EEG.

This device does not provide any diagnostic conclusion about the patient's condition to the user.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 GFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K092573